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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,912	12/16/2003	Herman E. Snyder	53285-US-CNT	8356
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NOVARTIS				
CORPORATE INTELLECTUAL PROPERTY				
ONE HEALTH PLAZA 104/3				
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EXAMINER				
BOECKMANN, JASON J				
ART UNIT		PAPER NUMBER		
3752				
MAIL DATE		DELIVERY MODE		
12/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/738,912

Applicant(s)

SNYDER ET AL.

Examiner

JASON J. BOECKMANN

Art Unit

3752

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26, 28-33, 35-45 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26, 28-33, 35-45 and 47-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 28-33, 35-45 and 47-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 26, 33 and 45, it is noted that there appears to be no support for the newly added limitation "wherein the first channel is not continued within the channel of the second channel." Nowhere in the specification as originally filed does the specification specifically

disclose that the first channel is not located within the channel of the second channel. Additionally, it appears from the figures (figs 214) that the first channel is located within the channel of the second channel.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 28-33, 35-45 and 47-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 26, 33 and 45, it is unclear what is meant by the term "the channel of the second channel." Does the second channel have a channel within it? Additionally, there is no antecedent basis for the term "the channel of the second channel".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 29-33, 36-41, 44-45 and 48-51 are rejected, as best understood, under 35 U.S.C. 102(b) as being anticipated by Platz et al. (6,051,256).

Platz et al. shows a spray drying system for forming a pharmaceutical formulation, the system comprising: an atomizer (57), the atomizer comprising a first, annular channel (100) through which a pharmaceutical liquid flows, the channel comprises a constriction (104) that has a diameter of less than .02 inches (column 14, line 1).for spreading the pharmaceutical liquid into a thin film in the channel, the atomizer further comprising a second channel (102) through which an atomizing gas flows, wherein the first channel is not contained within the second channel (it is noted that the first channel (100) is not within the channel of the second channel (102) in as much of a way as the first channel (60) of the present invention is not within the channel of the second channel (80)) and the second channel being positioned so that the atomizing gas impinges the liquid thin film to produce droplets; a drying chamber (50) to dry the droplets to form particles; and a collector (76) to collect the particles.

Regarding claims 29, 36 and 46, the device has a third channel for gas flow (the drying air of figure 2).

Regarding claims 31, 32, 38, 39, 49 and 50, the inlet gas stream has temperature of above 90 degrees C and the outlet of above 50 degrees C (see claim 10).

Regarding claim 40, the pharmaceutical liquid includes an active ingredient (column 8, line 60) and an excipient (column 9, line 35).

Regarding claims 41 and 51, the particles have a rugosity above 2 (column 6, line 2).

Regarding claim 44, the particles have a diameter of less than 20 micro meters (column 6, line 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 35, 42, 43 and 47 are rejected, as best understood, under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (6,051,256).

Regarding claims 28, 35 and 47, Platz et al. shows all aspects of the applicant's invention as in the rejection of claims 17 and 22 above, but fails to disclose that the constriction has a diameter of less than .005 inches. However, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make the diameter of the constriction less than .005 inches since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Additionally, it is well known in the art that the smaller the constriction, the faster the fluid velocity will be going through the restriction, as well as the more turbulent it will

be. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the constriction diameter less than .005, in order to increase the velocity and the turbulence of the fluid as it passes through the restriction point.

Regarding claims 42 and 43, Platz et al. shows all aspects of the applicant's invention as in the rejection of claim 33 above, but fails to specifically disclose that the particles have a density of less than $.5\text{g/cm}^3$, and that the glass transition temperature is above 35 Degrees C.

However, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use a material that makes the particles have a density of less than $.5\text{g/cm}^3$, and with a glass transition temperature of above 35 degrees C, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use of the device.

Response to Arguments

Applicant's arguments filed 11/24/2009 have been fully considered but they are not persuasive.

Regarding the applicant's arguments concerning the limitation, "wherein the first channel is not continued within the channel of the second channel," of claims 26, 33 and 45, the applicant argues that this limitation is not disclosed by Platz. However, it is noted that this limitation does not appear to be disclosed by the applicant. Please see the 112

first paragraph rejection above. It is noted that the first channel (100) is not within the channel of the second channel (102) in as much of a way as the first channel (60) of the present invention is not within the channel of the second channel (80).

Regarding the applicant's arguments concerning the 102 rejection under Platz, the applicant argues that Platz does not disclose a first channel comprising a constriction for spreading the pharmaceutical liquid into a thin film, or any preparation of a liquid thin film, or a separate second channel through which atomized gas flows and positioned so that the atomizing gas impinges the liquid thin film to produce droplets.

However, it is noted that the term "for spreading the pharmaceutical liquid into a thin film" is a recitation of the intended use of the first channel of the claimed invention. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, it is noted that Platz shows a first channel (100) having a constriction (104) (the constriction is shown in figure 3), which is identical in structure to the claimed invention. Since the applicant has not claimed any further structure that would create this thin film, it is the examiner's position is that the first channel and the constriction of Platz is fully capable of creating a thin liquid film and will spread the liquid into a thin liquid film in as much of a way as the claimed invention will spread the liquid into a thin liquid film.

Additionally, Platz shows a separate second channel (102) that directs a stream of atomizing gas towards the outlet of the first channel. The same argument as above

can be used here, since there is no further structure being claimed that differentiates the second channel of the claimed invention from the second channel of Platz. It is the examiner's position is that the second channel of Platz is fully capable of directing the atomizing gas toward the liquid film produced by the constriction and the first channel, and will therefore will produce droplets from the thin liquid film in as much of a way as the claimed invention will produce droplets from the thin liquid film.

Regarding the applicants rejection of claims 28, 35, 42, 43 and 47, the applicant argues that it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to change the constriction size to be less than .005 inches; however, the examiner respectfully disagrees. It is noted that the Platz reference teaches a constriction of .015 to .075 inches. However, it is well known in the art that the smaller the constriction, the faster the fluid velocity will be going through the restriction, as well as lower the fluid pressure will be. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the constriction diameter less than .005, in order to increase the velocity and decrease fluid pressure as it passes through the restriction point.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON J. BOECKMANN whose telephone number is

(571)272-2708. The examiner can normally be reached on 8:00- 5:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Len Tran can be reached on (571) 272-1184. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. J. B./
Examiner, Art Unit 3752
8/28/2009
/Len Tran/

Supervisory Patent Examiner, Art Unit 3752